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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,704	02/16/2006	Karlheinz Bortlik	3712036.00706	4852
29157 K&L Gates LLP P.O. Box 1135 CHICAGO, IL 60690	7590 05/27/2010		<div>EXAMINER</div> <div>MI, QIUWEN</div>	
			<div>ART UNIT</div> <div>1655</div>	<div>PAPER NUMBER</div>
			<div>NOTIFICATION DATE</div> <div>05/27/2010</div>	<div>DELIVERY MODE</div> <div>ELECTRONIC</div>

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

### Office Action Summary

**Application No.**

10/568,704

**Applicant(s)**

BORTLIK ET AL.

**Examiner**

QIUWEN MI

**Art Unit**

1655

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3-12, 14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) 6-8, 12, 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-5, and 9-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**Concentrate that DETAILED ACTION**

Applicant's reply filed on 5/12/2010 is acknowledged. Claims 2 and 13 are cancelled. Claims 1, 3-12, 14, and 15 are pending. Claims 6-8, 12, 14, and 15 are withdrawn as they are directed toward a non-elected invention group. **Claims 1, 3-5, and 9-11 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

**Claim Rejections –35 USC § 112, 2<sup>nd</sup>**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-5, and 9-11 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 2/24/2010, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Claims 1 (line 1), 9 (line 3), 10 (line 3), and 11 (line 2) recite "natural lycopene concentrate". The term "natural lycopene concentrate" in claims 1, and 9-11 is a relative term which renders the claim indefinite. The term "natural" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree and one of ordinary skill in the art would not be reasonably appraisal of the scope of the invention. For instance, on page 8 of the specification, Applicant recites "The supernatant is recovered and its

pH is adjusted to 7 with NaOH" (lines 5-10). Since NaOH does not exist in nature tomato, it is not clear whether the product could still be called "natural lycopene concentrate".

Thus, the metes and bounds of claims 1, and 9-11 are rendered uncertain by the phrase "natural lycopene concentrate" in claims 1, and 9-11 because "natural" could be a relative term.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Applicant argues that "As is clearly stated in the specification, "[t]he aim of the present invention is to provide a 'natural' product with increase bioavailability, that is to say that the product has only been subjected to technological treatments which do not modify its native characteristics." See, specification (Preliminary Amendment), page 3, paragraph 7. The specification further states that "the process of extraction according to the invention is simple, rapid and economical and at no time subject to the state of viability of the endoenzymes of the raw material." See, specification, page 4, paragraph 8. As such, the skilled artisan would immediately appreciate that a "natural" lycopene concentrate is a lycopene concentrate that has not be subjected to technological treatments that would modify its native characteristics. Indeed, the specification clearly defines a "natural" lycopene concentrate as a lycopene concentrate that "has only been subjected to technological treatments which do not modify its native characteristics." Thus, not only is the phrase "natural lycopene concentrate" explicitly defined in the specification, but the skilled artisan would immediately appreciate what it means to modify the native characteristics of a lycopene concentrate. For at least the above mentioned reasons,

Applicants respectfully submit that Claims 1, 3-5 and 9-11 fully comply with the requirements under 35 U.S.C. § 112, second paragraph" (page 2, last paragraph bridging page 3).

This is not found persuasive. As indicated in the last Office Action, "natural" is a relative term, people might consider that only tomato concentrate going through squeezing or pressing procedure is considered as "natural", and most people would consider when "NaOH" is added to a tomato concentrate (see Specification, lines 5-10), it is not "natural", as a natural tomato doesn't contain NaOH solution. Therefore, the metes and bounds of claims 1, and 9-11 are rendered uncertain by the phrase "natural lycopene concentrate" in claims 1, and 9-11 because "natural" could be a relative term.

### **Claim Rejections –35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-5, and 9-11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kesharlal et al (US 6,224,876).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 2/24/2010, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Kesharlal et al teach fresh hard, good quality reddish colored "Desi Red" carrots with a smooth surface, excluding those that were found defective, were selected and washed thoroughly with water. The sorted and washed carrots (1.0 kg) were subjected to crushing in a fruit mill to provide a comminution which was subjected to pressing through a filter press for the purpose of separating the pulp from the juice to provide a juice (ca. 600 ml) (thus water soluble at room temperature, thus the concentrate is extracted from a lycopene-containing material without using a solvent, thus a solid-liquid separation). To the juice, 3 g of adipic acid was added with stirring (thus not more than 10% organic acid). To the resulting mixture was added 60 g of sorbitol and the mixture was subjected to centrifuging to provide paste (ca. 17.2 g). The paste was dried under high vacuum. Pulverizing of the solid material and sieving gave the carotenoid powder (thus ingestible, thus in a powder form) of the invention (3.8 g) (col 7, Example 1). The composition of the product is given below. Composition per 100 g product from "Desi Red" carrots (Example 1): beta-Carotene 530 mg; alpha-Carotene 27 mg, Lycopene 700 mg (thus 7 mg/g; thus at least 1 mg of lycopene per g); Lutein/Xeaxanthin 15 mg; Total Carotenoids 3750 mg; Proteins 32.8 g (thus 32.8%); Carbohydrates 4 g; Phosphorus 647 mg; Lipids 15.3 g (thus 15.3%); Vitamin C 22 mg; Vitamin B1 5 mg; Vitamin B2 1 mg; Iron 95 mg; Zinc 1 mg; Manganese 1 mg; Magnesium 162 mg; Calcium 1.381 g; Potassium 1.99 g; Sodium 1.99 g; Total Minerals (Ash value) 6.87 g (col 8, 1<sup>st</sup> table). In Example 2, Kesharlal et al also teach the "Bangalore local" carrots were processed according to the procedure described in Example 1. Composition per 100g product from "Bangalore local" carrots contain 30.3 g lipids (thus at least 30% lipid compounds), and protein 31.5 g (thus 31.5%). Even though Kesharlal et al do not explicitly teach not more than 30% protein, in Example 3, Kesharlal et al teach the protein range

from different supplies contain 10-50% protein. Kesharlal et al further teach 5 participants sensitive to continuous exposure to sunlight and suffering from skin erythema on longer exposure were administered the tablets over a period of four weeks. Significant reduction of the symptoms induced by long exposure were observed (col 12, lines 20-25) (thus a cosmetic composition (that is taken orally) for slowing aging of the skin and/or to combat skin damage which may be caused by exposure to ultraviolet light). Kesharlal et al further teach the tablets (thus a composition which can be ingested orally, thus a dietary supplement) were prepared by blending nutrient-rich carotenoid powder with sucrose and Microcrystalline cellulose, granulating with Starch Gelatin paste, drying, lubricating with Talc, Magnesium stearate and Colloidal silicon dioxide followed by compression into tablet (col 10, lines 15-20).

Kesharlal et al do not explicitly teach a natural lycopene concentrate containing not more than 30% protein.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to vary the amount of the protein in a natural lycopene concentrate since in Example 3, Kesharlal et al teach different supplies contain 10-50% protein. Therefore, it would have been obvious for one of the ordinary skill in the art to choose a particular protein content carrot from different carrot species or supplier. Since Kesharlal et al yielded beneficial results for producing lycopene containing product, one of ordinary skill in the art would have been motivated to make and use the invention.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant argues that “For example, *Kesharlal* fails to disclose or suggest natural lycopene concentrates comprising at least 1 mg of lycopene per g of the said concentrate, not more than 30% proteins, not more than 30% polysaccharides, not more than 10% organic acids, and at least 30% of lipid compounds, wherein the concentrate is ingestible, in powder form and isolated from fibers and other insoluble compounds by solid-liquid separation, and wherein the concentrate is extracted from a lycopene-containing material without using a solvent as required, in part, by independent Claims 1 and 10-11. Instead, *Kesharlal* is entirely directed to pharmacologically and biologically active compositions containing carotenoids, micro and macro nutrients and a process for their preparation from carrots. See, *Kesharlal*, Abstract; column 1, lines 8-12” (page 3, last paragraph bridging page 4).

Applicant also argues that “The Patent Office admits that *Kesharlal* fails to disclose or suggest not more than 30% protein, but states that because *Kesharlal* “teaches a protein range from about 10-50% protein that it would have been obvious for one of ordinary skill in the art to choose a particular protein content carrot from [a] different carrot species or supplier.” See, Office Action, page 4, line 19- page 5, line 15. However, Applicants respectfully disagree and submit that not only does *Kesharlal* fails to disclose or suggest the natural lycopene concentrates of the present claims, but *Kesharlal* teaches away from the presently claimed amounts of protein” (page 4, 2<sup>nd</sup> paragraph).



Applicant further argues that “For example, as admitted by the Patent Office, *Kesharlal* fails to disclose or suggest not more than 30% protein as required, in part, by the present claims. Indeed, since *Kesharlal* “teaches a protein range from about 10-50%,” *Kesharlal* clearly discloses that protein amounts in the range of 30-50% are acceptable. However, this is in direct contrast to the present claims that explicitly require “no more than 30% proteins.” As such, the disclosure of *Kesharlal* clearly teaches away from the present claims. For at least the above-mentioned reasons, Applicants respectfully submit that *Kesharlal* is deficient with respect to the present claims” (page 4, 3<sup>rd</sup> paragraph).

This is not found persuasive. First of all, *Kesharlal* teaches every limitation of the claims, except “not more than 30% protein”. If *Kesharlal* teaches that part, it would be a 102 rejection, not a 103. Secondly, *Kesharlal* teaches a protein range from about 10-50%, which overlaps with the claimed “not more than 30% protein”, and it would be obvious for one of the ordinary skills in the art to choose any concentration from that range, including “not more than 30% protein”. Further more, *Kesharlal* does not “teach away” from the claimed invention, as it does not say, “more than 30% of the protein will not work”. Applicant argues that the cited reference teaches away from the claimed invention. According to MPEP 2123, “Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). “A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use.” In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994) (The invention was directed to an epoxy impregnated fiber-reinforced printed circuit material. The applied prior art reference taught a printed circuit

material similar to that of the claims but impregnated with polyester-imide resin instead of epoxy. The reference, however, disclosed that epoxy was known for this use, but that epoxy impregnated circuit boards have “relatively acceptable dimensional stability” and “some degree of flexibility,” but are inferior to circuit boards impregnated with polyester-imide resins. The court upheld the rejection concluding that applicant’s argument that the reference teaches away from using epoxy was insufficient to overcome the rejection since “Gurley asserted no discovery beyond what was known in the art.” 27 F.3d at 554, 31 USPQ2d at 1132.). Furthermore, “[t]he prior art’s mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed...” In re Fulton, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004).

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

### **Conclusion**

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Qiuwen Mi/

Examiner, Art Unit 1655